

**REMARKS**

This application has been reviewed in light of the Office Action dated March 27, 2002. Claims 1-30 are pending in the application. By the present amendment, claims 1, 12, 19, 23 and 28 have been amended in a manner, which is believed to overcome the rejections in the Office Action.

Claims 1, 12-14 and 18-30 are rejected under 35 U.S.C. 102(b)

Claims 1, 12-14 and 18-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Cartmell et al. (U.S. Patent No. 5,160,328). Applicants respectfully submit that amendments contained herein further define applicants invention so that claims 1, 12-14 and 18-30 are not anticipated by Cartmell et al. under 35 U.S.C. 102(b).

Claim 1 has been amended to more accurately described and emphasize the Applicants' invention. The modifying term "self supporting" is added to claim 1 to further indicate that the hydrogel composition made by the method of the present invention has advantageous strength that is not seen in the prior art. The hydrogel of Cartmell is of a composition not having the resilience of the instant application and unlike the instant application the hydrogel of Cartmell is deposited upon a substrate. The Cartmell patent does not disclose a self supporting hydrogel as disclosed and claimed by the Applicants. Therefore, Applicants respectfully submit that claim 1 and all claims depending therefrom (claims 2-11) are not anticipated by Cartmell et al. under 35 U.S.C. 102(b).

Claim 12 has been amended to more clearly define the method of the invention for producing a "self supporting resilient" hydrogel composition. As amended, claim 12 recites a method including a step of forming a first solution by blending a polyurethane prepolymer with a polyalkyl diol, a step of forming a second solution by combining water and an alkyl diol and an accelerator, a step of adding an additive agent to the first or second solution, and a step of combining the first solution with the second solution

The amendments to claim 12 further define the Applicants' invention and emphasizes the self supporting resilient nature of Applicants' hydrogel. Unlike the hydrogel disclosed in Cartmell, Applicants' hydrogel wound dressing functions without additional components such as support layers or substrates. The Cartmell hydrogel does not have sufficient strength to function without support layers or substrates. This need for a supported hydrogel is disclosed throughout the drawings, description and claims of Cartmell. For instance, this need for a supported hydrogel is disclosed in the Cartmell specification as follows:

“[i]t is preferable to have a support layer made of a polymeric film and a second support layer made from, for example, scrim adhesively secured to the support layer, both of which are interposed between the hydrogel layer and the substrate”

(See Cartmell at Column 2, lines 44 to 48).

Applicants respectfully submit that the method of claim 12 and the compositions produced according to the method as claimed in claims 13-14, as amended, are not disclosed or suggested in Cartmell, and accordingly are not anticipated under 35 U.S.C. 102(b).

Claims 19 and 28 have been amended to claim a hydrogel composition having a thickness of approximately 2.0 to 2.5 cm. This range of thickness is outside the range of thickness found in the Cartmell patent that discloses a composition from 0.6 to 1.5 cm thick. Claims 18, 20, 22, 24, 25, 26, 27, 29 and 30 are directed to various shapes that are molded for a variety of uses. These various shapes and uses are not possible with a non-self supporting hydrogel. Applicants respectfully suggest that the self supporting hydrogel required by the shapes in the above claims is not disclosed or suggested by Cartmell.

Claim 23 has been amended to more accurately describe and emphasize Applicants' invention. The modifying term “self supporting” is added to claim 23 to further indicate that the hydrogel composition made by the method of the present disclosure has advantageous strength that is not seen or suggested in the prior art.

Applicants respectfully submit that the claimed compositions and methods of producing those compositions are not anticipated by Cartmell under 35 U.S.C. 102(b). It is respectfully requested that these rejections based upon 35 U.S.C. 102(b) be withdrawn.

Claims 1-11 and 12-17 are rejected under 35 U.S.C. 103(a)

Claims 1-11 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. (U.S. Patent No. 5,160,328) in view of Hennink et al. (U.S. Patent No. 5,219,325, the '325 patent).

Claim 1 has been amended to more accurately described and emphasize Applicants' invention. The modifying term "self supporting" is added to claim 1 to further indicate that the hydrogel composition as made by the method of the present invention has advantageous strength, and therefore, does not require a substrate for support, unlike what is required by the prior art.

Claim 12 has also been amended to particularly emphasize that the "self supporting resilient" hydrogel wound dressing of the instant invention has sufficient mechanical strength to be applied to a wound without requiring support by a substrate material or support layers. Neither the '328 patent to Cartmell et al. nor the '325 patent to Hennink et al., considered alone or in combination teach or suggest the invention including all of the limitations of claims 1 and 12, as amended, and described above. Furthermore, the disclosure of the present invention at page 10, line 17 to page 11, line 9 teaches the unexpectedly superior results achieved by the present invention, for instance, strength and flexibility, transparency and water absorption characteristics, which are not achieved or suggested by Cartmell and/or Hennink et al.

The Examiner suggests that it would have been obvious to one of ordinary skill in the art to use the agents disclosed by Hennink et al. and the invention of Cartmell et al. to obtain a hydrogel composition containing such agents for the purpose of controlling infection in opened wounds. However, in the instant case, neither cited reference contains a self supporting resilient hydrogel, absent a supporting structure. Since the self supporting nature of the inventive hydrogel is not found in the art, it is fair to assume that in raising the obviousness rejection, the Examiner gleaned knowledge from the Applicants disclosure contrary to well-established legal

principles. Applicants respectfully request that the rejected claims be favorably reconsidered in light of well-established legal principles, which provide,

*"That one skilled in the art is not synonymous with obviousness.... That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the reference to make the claimed invention" Ex parte Levengood, 28 USPQ 2d 1300 (Bd. Pat. App. & Inter. 1993).*

The particular combination of the cited references, which the Examiner makes in an attempt to arrive at the Applicant's invention, is neither taught nor suggested by either reference. The references, alone or in combination, because of the differences in the features of each as discussed above, do not provide "sufficient impetus" to support the combination that the Examiner makes to effect the obviousness rejection. Furthermore, the combination that the Examiner suggests does not arrive at the Applicants' invention.

Applicants therefore respectfully submit that claim 1 and its dependant claims 2-11, and claim 12 and its dependant claims 13-17 are not obvious under 35 U.S.C. 103(a) over Cartmell et al. in view of Hennink et al.

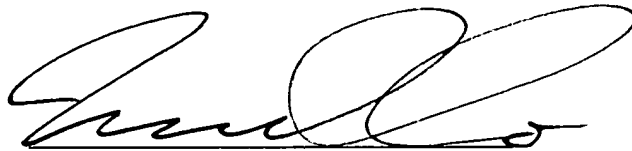
A rejection was made to claims 1-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-75 of U.S. Patent No. 6,180,132 (the '132 patent). The Applicants would suggest that the claimed subject matter of the rejected claims differs from that of the claims within the '132 patent. In the alternative, upon notification of allowable subject matter, the Applicants will execute an acceptable terminal disclaimer.

Accordingly, it is believed that in view of the above comments and further amendments to the claims, all claims are now in condition for allowance, and therefore reconsideration and allowance are earnestly solicited. If the Examiner feels that a telephone conference would expedite prosecution of this case, or resolve any remaining issues, the Examiner is invited to contact the undersigned at (617) 856-8145.

In accordance with 37 CFR 1.121(c)(1)(ii), a marked up version of the amended claims is attached as Appendix A.

Please charge any deficiency as well as any other fee(s), which may become due at any time during the pendency of this application, or credit any overpayment of such fee(s) to Deposit Account No. 50-0369. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 50-0369 therefor.

Respectfully submitted,



Date: July 29, 2000

Mark S. Leonardo  
Reg. No.: 41,433  
Attorney for Applicant(s)  
Customer No. 21710  
BROWN RUDNICK BERLACK ISRAELS LLP  
One Financial Center  
Boston, MA 02111  
Tel: (617) 856-8145  
Fax: (617) 856-8201

Appendix A

1. A hydrogel composition comprising from 5 percent to 30 percent by weight of a polyurethane prepolymer, from 3 percent to 45 percent by weight of one or more [alcohols] polyalkyl diols [selected from the group consisting of polyethylene glycol, polypropylene glycol], [and] from 3 percent to 45 percent by weight of one or more alkyl diols [propylene glycol], and the balance water, accelerator and an additive, wherein the hydrogel is self supporting. NM

12. A method of producing a self supporting resilient hydrogel composition comprising:  
forming a first solution of polyurethane prepolymer and polyakyl diol selected from the group consisting of polyethylene glycol, polypropylene glycol and polybutylene glycol; NM  
forming a second solution of water, [propylene glycol] polyakyl diol and accelerator;  
adding an additive agent to either said first solution or said second solution; and  
combining said first solution with said second solution.

19. The method of claim 12 wherein said combined first and second solutions are cast and molded to form a wound dressing approximately [0.01] 2 to [1.0] 2.5 [inch] cm thick.

23. A hydrogel composition comprising a polyurethane prepolymer, one or more alcohols selected from the group consisting of polyethylene glycol, polypropylene glycol and propylene glycol, and the balance water, and an accelerator, wherein the hydrogel is self supporting.

28. The hydrogel composition of claim 23 wherein said hydrogel composition is cast and molded to form a dressing approximately [0.01] 2 to [1.0] 2.5 [inch] cm thick.